

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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BARBARA ZAROWITZ, Derivatively On :  
Behalf Of PFIZER, INC., :

Plaintiff, :

v. :

HENRY A. MCKINNEL, WILLIAM C. :  
STEERE, JR., JEAN-PAUL VALLES, :  
MICHAEL S. BROWN, STANLEY O. :  
IKENBERRY, FRANKLIN D. RAINES, M. :  
ANTHONY BURNS, ROBERT N. BURT, W. :  
DON CORNWELL, WILLIAM H. GRAY III, :  
CONSTANCE J. HORNER, WILLIAM R. :  
HOWELL, GEORGE A. LORCH, DANA G. :  
MEAD, RUTH J. SIMMONS, :

Defendants, :

-and- :

PFIZER, INC., a Delaware corporation, :

Nominal Defendant. :

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**ECF CASE**

**Civil Action No. 04 CV 10075 (RCC)**

**JURY TRIAL DEMANDED**

**SHAREHOLDER VERIFIED DERIVATIVE COMPLAINT FOR BREACH  
OF FIDUCIARY DUTY, ABUSE OF CONTROL, GROSS MISMANAGEMENT,  
WASTE OF CORPORATE ASSETS, AND UNJUST ENRICHMENT**

Plaintiff, by her attorneys, brings this action on behalf of nominal defendant Pfizer, Inc. (“Pfizer” or the “Company”), and alleges the following based upon personal knowledge as to herself and her activities, and based upon an investigation conducted by her counsel for all other matters. That investigation has included a thorough review and analysis of public documents, United States Securities and Exchange Commission (“SEC”) and United States Food and Drug Administration (“FDA”) filings, court filings, press releases, medical journal articles, patent documents and news articles concerning Pfizer, and the other facts as set forth herein.

**NATURE OF THE ACTION**

1. This is a shareholders' derivative action brought in the right of, and for the benefit of, nominal defendant Pfizer, Inc. ("Pfizer" or the "Company") against its Board of Directors (the "Board") and certain top current and former officers to remedy defendants' breaches of fiduciary duties and other violations of law which have inflicted millions of dollars in damages upon Friedman's reputation, goodwill and standing in the business community and have exposed it to millions of dollars in potential claims for products liability as well as liability for violations of state and federal law. This action arises out of defendants' causing Pfizer to continue to market two of its top products – Celebrex and Bextra – despite studies and knowledge that the products had severe and undisclosed side effects and to issue false and misleading statements about the Company's business, prospects for the sales and safety of Celebrex and Bextra products, and Pfizer's business prospects November 1, 2000 and December 14, 2004 (the "Relevant Period"). Upon revelation of the truth about the Company's Celebrex and Bextra products, these products were removed from the market by the FDA, Pfizer's business prospects collapsed and its stock price and market capitalization were decimated. Defendants' misconduct has caused severe, irreparable, injury and damages to the Company, particularly to its reputation and goodwill in the investment and business community, have subjected the Company to a plethora of product liability suits, including wrongful death actions, numerous securities class actions and investigations by the FDA.

2. Toward the end of the Relevant Period, a series of factual revelations from several sources caused the market to gradually perceive the truth about Pfizer's Bextra and Celebrex products. Then, on the morning of December 17, 2004, before the stock market opened, Pfizer shocked the market after revealing that, indeed, it had found an increased risk of heart attacks in patients taking its Celebrex. These revelations caused Pfizer's share prices to open for trading on

December 17, 2004, down \$3.88 per share, a drop of 13.3%, from the closing price of \$28.98 per share the previous day, destroying more than \$21 billion in market capitalization in a single day

### **JURISDICTION AND VENUE**

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a)(2), because complete diversity exists between the plaintiff and each defendant, and the amount in controversy exceeds \$75,000. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. §1367(a) (2002).

4. This action is not a collusive one designed to confer jurisdiction on a court of the United States which it would not otherwise have.

5. Venue is proper in this District because many of the acts complained of, including the dissemination of materially false and misleading statements and reports prepared by or with the participation, acquiescence, encouragement, cooperation, or assistance of defendants, occurred, at least in part, in this District. Additionally, Pfizer was headquartered in this district at all times relevant to this action.

### **PARTIES**

6. Plaintiff Zarowitz, a resident of the State of Michigan, is and was at all relevant times complained of herein, a shareholder of nominal defendant Pfizer.

7. Nominal defendant Pfizer, is a Delaware corporation which engaged in the development, marketing and distribution of pharmaceutical drugs worldwide. The Company is headquartered at 235 East 42nd Street, New York, New York 10017.

8. Defendant Henry A. McKinnel ("McKinnel") has been since May, 2001 Chairman of the Board and since January 2001 the Chief Executive Officer. From 1999 to May 2001 he was the President of the Company. From January 1997 to April 2001, McKinnel was

President, Pfizer Pharmaceuticals Group, the principal operating division of the Company, Pfizer's Chief Operating Officer from May 1999 to December 2000 and Executive Vice President from 1992 to 1999. As an officer and director of Pfizer, McKinnel owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as CEO and Chairman of the Board, McKinnel also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties McKinnel owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. McKinnel is a citizen of the State of New York.

9. Defendant William C. Steere, Jr ("Steere") has been Chairman Emeritus of Pfizer Inc. since July 2001 and has been since a director of Pfizer since 1987. Steere was Chairman of Pfizer's Board from 1992 to April 2001 and Chief Executive Officer from February 1991 to December 2000. As an officer and director of Pfizer, Steere owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as CEO and Chairman of the Board at relevant times, Steere also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Steere owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by

purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Steere is a citizen of the State of New York.

10. Defendant Jean-Paul Vallès (“Vallès”) was, at all relevant times, a director of Pfizer, and a member of the board’s Audit Committee. Vallès, is Chairman Emeritus of Minerals Technologies Inc. (MTI), and was previously Chairman and CEO of Minerals Technologies Inc., when MTI became a publicly traded company through an initial public offering from Pfizer Inc. on October 23, 1992. Vallès joined Pfizer in 1968 as an Economist and Assistant to the Chairman. In 1970, he was appointed Director of Corporate Planning and Information Services, and, in 1972, was elected Controller of the company. In 1980, he was elected to the Board of Directors of Pfizer Inc., and became Vice President-Finance in June 1980 and was elected Senior Vice President-Finance in January 1989. In April 1989, he was given responsibility for Pfizer Specialty Minerals Group, the operations that now comprise Minerals Technologies Inc. In August 1990, he was elected Senior Vice President and assumed the added responsibility for the company’s Animal Health group. He was elected Executive Vice President in February 1991 when he also became responsible for the Pfizer Specialty Chemicals Group. On January 1, 1992, Mr. Vallès was given the additional responsibility for the Pfizer Hospital Products group and, on March 1, 1992, he was elected Vice Chairman of Pfizer Inc. As a director of Pfizer, Vallès owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Audit Committee, Vallès also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Vallès to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions

complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Mead is a citizen of the State of New York.

11. Defendant Michael S. Brown (“Brown”) was, at all relevant times, a director of Pfizer, Chairman of the board’s Science and Technology Committee and member of the Corporate Governance Committee. Brown also has been the Distinguished Chair in Biomedical Sciences since 1989 and the Regental Professor since 1985 at the University of Texas Southwestern Medical Center at Dallas. Brown is the co-recipient of the Nobel Prize in Physiology or Medicine in 1985 and the National Medal of Science in 1988. As a director of Pfizer, Brown owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Science and Technology Committee and the Corporate Governance Committee, Brown also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company particularly, as a member of the Science and Technology Committee, with respect to scientific studies and information pertinent to Pfizer’s key products, and ensuring the Company’s public statements and governmental filings were truthful and accurate. Rather than fulfill these important fiduciary duties Brown owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As Chairman of Pfizer’s Science and Technology Committee, Brown was directly responsible for “determine[ing] whether there is sufficient and ongoing external review from world-class experts across both research and

development, pertaining to the Company's therapeutic areas," which included research with regard to therapeutic uses of COX-2 inhibitors, so Brown is a direct participant in the wrongdoing. Brown is a citizen of the State of Texas.

12. Defendant Stanley O. Ikenberry ("Ikenberry") was, at all relevant times, a director of Pfizer, and member of the board's Science and Technology Committee, Corporate Governance Committee and Executive Committee. As a director of Pfizer, Ikenberry owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Science and Technology Committee, Executive Committee and the Corporate Governance Committee, Ikenberry also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company particularly, as a member of the Science and Technology Committee, with respect to scientific studies and information pertinent to Pfizer's key products, and ensuring the Company's public statements and governmental filings were truthful and accurate. Rather than fulfill these important fiduciary duties Ikenberry owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As a member of Pfizer's Science and Technology Committee, Ikenberry was directly responsible for "determine[ing] whether there is sufficient and ongoing external review from world-class experts across both research and development, pertaining to the Company's therapeutic areas," which included research with regard to therapeutic uses of COX-2 inhibitors, so Ikenberry is a direct participant in the wrongdoing. Ikenberry is a citizen of the State of Illinois.

13. Defendant Franklin D. Raines (“Raines”) was, at all relevant times, a director of Pfizer, and member of the board’s Science and Technology Committee and Compensation Committee. As a director of Pfizer, Raines owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Science and Technology Committee and the Compensation Committee, Raines also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company particularly, as a member of the Science and Technology Committee, with respect to scientific studies and information pertinent to Pfizer’s key products, and ensuring the Company’s public statements and governmental filings were truthful and accurate. Rather than fulfill these important fiduciary duties Raines owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As a member of Pfizer’s Science and Technology Committee, Raines was directly responsible for “determine[ing] whether there is sufficient and ongoing external review from world-class experts across both research and development, pertaining to the Company’s therapeutic areas,” which included research with regard to therapeutic uses of COX-2 inhibitors, so Raines is a direct participant in the wrongdoing. Raines is a citizen of Washington, D.C.

14. Defendant M. Anthony Burns (“Burns”) was, at all relevant times, a director of Pfizer, and Chairman of the board’s Compensation Committee and a member of the Executive Committee. As a director of Pfizer, Burns owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a



Chairman of the Compensation Committee and member of the Executive Committee, Burns also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Burns owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Burns is a citizen of the State of Florida.

15. Defendant Robert N. Burt (“Burt”) was, at all relevant times, a director of Pfizer, and Chairman of the board’s Audit Committee. As a director of Pfizer, Burt owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a Chairman of the Audit Committee, Burt also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Burt owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Burt is a citizen of the State of Illinois.

16. Defendant W. Don Cornwell (“Cornwell”) was, at all relevant times, a director of Pfizer, and a member of the board’s Audit Committee. As a director of Pfizer, Cornwell owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Audit Committee, Cornwell also

assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Cornwell owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Cornwell is a citizen of the State of New York.

17. Defendant William H. Gray III (“Gray”) was, at all relevant times, a director of Pfizer, and a member of the board’s Corporate Governance Committee. As a director of Pfizer, Gray owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Corporate Governance Committee, Gray also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Gray owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Gray is a citizen of the State of Pennsylvania.

18. Defendant Constance J. Horner (“Horner”) was, at all relevant times, a director of Pfizer, and Chair of the board’s Corporate Governance Committee and a member of the Executive Committee. As a director of Pfizer, Horner owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as Chair of the Corporate Governance Committee and member of the Executive

Committee, Horner also assumed important managerial responsibilities at Pfizer which required her to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Horner owed to Pfizer and its shareholders she, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached her fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Horner is a citizen of Washington, D.C.

19. Defendant William R. Howell (Howell”) was, at all relevant times, a director of Pfizer, and a member of the board’s Audit Committee. As a director of Pfizer, Howell owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Audit Committee, Howell also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Howell owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Howell is a citizen of the State of Texas.

20. Defendant George A. Lorch (“Lorch”) was, at all relevant times, a director of Pfizer, and a member of the board’s Compensation Committee. As a director of Pfizer, Lorch owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Compensation Committee, Lorch also assumed important managerial responsibilities at Pfizer which required him to be well

informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Lorch owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Lorch is a citizen of the State of Florida.

21. Defendant Dana G. Mead (“Mead”) was, at all relevant times, a director of Pfizer, and a member of the board’s Compensation Committee. As a director of Pfizer, Mead owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Compensation Committee, Mead also assumed important managerial responsibilities at Pfizer which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Mead owed to Pfizer and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Mead is a citizen of the State of Connecticut.

22. Defendant Ruth J. Simmons (“Simmons”) was, at all relevant times, a director of Pfizer, and a member of the board’s Corporate Governance Committee. As a director of Pfizer, Simmons owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of the Corporate Governance Committee, Simmons also assumed important managerial responsibilities at Pfizer which required her to be well informed about the day-to-day operations of the Company. Rather than

fulfill these important fiduciary duties Simmons owed to Pfizer and its shareholders she, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached her fiduciary duties to the shareholders of Pfizer by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Simmons is a citizen of Rhode Island.

23. The Defendants identified above in ¶¶8-23 are collectively referred to hereinafter as the “Individual Defendants,” or as the “Director Defendants.”

### **DUTIES OF THE INDIVIDUAL DEFENDANTS**

24. By reason of their positions as officers, directors and/or fiduciaries of Pfizer and because of their ability to control the business and corporate affairs of Pfizer, the Individual Defendants owed Pfizer and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage Pfizer in a fair, just, honest and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Pfizer and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

25. Each director and officer of the Company owes to Pfizer and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with regard to the Company’s products, revenue, margins, operations, performance, management, projections and forecasts so that the market price of the Company’s stock would be based on truthful and accurate information.

26. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Pfizer, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with Pfizer, each of the Individual Defendants had access to adverse non-public information about the financial condition, operations, and improper representations of Pfizer.

27. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of Pfizer, and was at all times acting within the course and scope of such agency.

28. To discharge their duties, the officers and directors of Pfizer were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Pfizer were required to, among other things:

- (a) refrain from acting upon material inside corporate information to benefit themselves;

- (b) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

- (c) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(d) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's products and studies relevant thereto;

(e) remain informed as to how Pfizer conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices and make such disclosures as necessary to comply with federal and state securities laws; and

(f) ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.

29. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Pfizer, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and/or directors of the Company during the Relevant Period has been ratified by the remaining Individual Defendants who collectively comprised all of Pfizer's Board during the Relevant Period.

30. The Individual Defendants breached their duties of loyalty and good faith by allowing defendants to cause or by themselves causing the Company to misrepresent its

products, financial results and prospects, as detailed herein infra, and by failing to prevent the Individual Defendants from taking such illegal actions. In addition, as a result of defendants' illegal actions and course of conduct during the Relevant Period, the Company is now the subject of numerous product defect actions, several class action law suits that allege violations of federal securities laws and an ongoing investigation by the FDA. As a result, Pfizer has expended and will continue to expend significant sums of money. Such expenditures include, but are not limited to:

- (a) Costs incurred to carry out internal investigations, including legal fees paid to outside counsel;

- (b) Costs incurred to defend and settle product defect actions;

- (c) Costs incurred to conduct additional testing and research with regard to the safety and efficacy of its COX-2 inhibitor products, including Celebrex and Bextra;

- (d) Costs incurred in public relations and advertising to convince the public of the safety of the Company's products, even though it refuses to remove its COX-2 inhibitor products, including Celebrex and Bextra, from the marketplace; and

- (e) Costs incurred in investigating and defending Pfizer and certain officers in the class actions, plus potentially millions of dollars in settlements or to satisfy an adverse judgment.

31. Moreover, these actions have irreparably damaged Pfizer's corporate image and goodwill. For at least the foreseeable future, Pfizer will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that Pfizer's ability to raise equity capital or debt on favorable terms in the future is now impaired.



### **CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION**

32. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breach of their respective duties.

During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to and did: (i) conceal the fact that the Company was improperly marketing its COX-2 inhibitor products, including Celebrex and Bextra, as safe and effective, in order to allow Defendants to artificially inflate the price of the Company's shares; (ii) maintain the Individual Defendants' executive and directorial positions at Pfizer and the profits, power and prestige that the Individual Defendants enjoyed as a result of these positions; and (iii) deceive the investing public, including shareholders of Pfizer, regarding the Individual Defendants' management of Pfizer's operations, the Company's financial health and stability, and future business prospects, specifically related to the Company's sales of its COX-2 inhibitor products, including Celebrex and Bextra throughout the Relevant Period. In furtherance of this plan, conspiracy and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.

33. The Individual Defendants engaged in a conspiracy, common enterprise and/or common course of conduct commencing by at least November, 2000 and continuing thereafter. During this time the Individual Defendants caused the Company to conceal the true fact that Pfizer was misrepresenting its products and its financial prospects based upon the sale of its key COX-2 inhibitor products, including Celebrex and Bextra. In addition, defendants also made

other specific, false statements about Pfizer's financial performance and future business prospects, as alleged herein.

34. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment; to conceal adverse information concerning the Company's operations, financial condition and future business prospects; and to artificially inflate the price of Pfizer common stock so they could: (i) dispose of over million of dollars worth of their personally held stock; (ii) protect and enhance their executive and directorial positions and the substantial compensation and prestige they obtained as a result thereof; and (iii) use the artificially inflated Company stock to acquire companies in stock-for-stock transactions.

35. The Individual Defendants accomplished their conspiracy, common enterprise and/or common course of conduct by causing the Company to purposefully, recklessly or negligently misrepresent its products and its financial prospects based upon the sale of these products. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary and substantial participant in the conspiracy, common enterprise and/or common course of conduct complained of herein.

36. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that

wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

37. Pfizer, Inc. (“Pfizer”) is a research-based global pharmaceutical company which develops, manufactures, and markets prescription medicines. Pfizer is based in New York and incorporated under the laws of Delaware. A major portion of Pfizer’s revenue comes from the manufacture and sale of two medications: celecoxib, sold by Pfizer under the brand name Celebrex, and valdecoxib, sold by Pfizer under the brand name Bextra. Celebrex was approved by the Food and Drug Administration (“FDA”) in 1998, while Bextra was approved in 2001. In 2003, sales of Celebrex totaled approximately \$1.8 billion. In 2003, sales of Bextra totaled approximately \$687 million. Pursuant to the Company quarterly report for 3Q:04 filed with the SEC on Form 10-Q, collectively, Pfizer’s sales of Celebrex and Bextra represented over 10% of the Company’s pharmaceutical sales, and was greater than the total sales by the Company’s consumer health care and animal care segments.

38. Both Celebrex and Bextra are part of a family of medications known as COX-2 inhibitors used to treat chronic pain resulting from arthritis. COX-2 is an enzyme occurring naturally in the body which is thought to cause arthritis pain and inflammation. COX-2 inhibitors target this enzyme and are thereby purported to reduce the symptoms of osteoarthritis and rheumatoid arthritis.

39. The only other COX-2 inhibitor approved by the FDA – rofecoxib, sold under the brand name Vioxx by Merck – was voluntarily withdrawn from circulation by Merck in September 2004 after a clinical study meant to determine the gastrointestinal safety profile of

Vioxx unintentionally revealed an increased cardiovascular risk in users following 18 months of continuous use. Cardiac problems related to the use of Cox-2 inhibitors such as Celebrex and Bextra have been documented since at least 2000. A study published in the August 29, 2000 Proceedings of the National Academy of Sciences entitled Cyclooxygenase-2 Mediates the Cardioprotective Effects of the Late Phase of Ischemic Preconditioning in Conscious Rabbits by Dr. Ken Shinmura et al. (“NAS Study”) analyzed the “late phase of ischemic preconditioning” (“Late PC”) -- an adaptive response of the heart to mild cardiac events conferring resistance to subsequent cardiac problems. Late PC is beneficial for patients recovering from adverse cardiac events.

40. The NAS study determined that COX-2 plays an “essential role in the cardioprotection” afforded by Late PC, and that COX-2 inhibitors – like Celebrex and Bextra -- entirely prevented these cardioprotective effects. This article concluded that COX-2 was a “cardioprotective protein,” offering beneficial cardiac effects, and that drugs blocking this cardioprotective enzyme may neutralize these cardioprotective effects.

41. This same study noted that the ability of rabbits to withstand temporary experimental coronary artery occlusion (experimental heart attack) was significantly impaired by treatment with Celebrex, as that drug “*completely block[ed] the cardioprotective effects* of late PC against both myocardial stunning and myocardial infarction.” (Emphasis added). This indicated that “COX-2 activity is necessary for [Late PC] to occur.”

42. The August 14, 2001 issue of Circulation contained an article entitled Effects of Selective Cyclooxygenase-2 Inhibition on Vascular Responses and Thrombosis in Canine Coronary Arteries by Dr. James K. Hennen et al. (“Circulation Study”) presenting the findings of a study analyzing the effects of COX-2 inhibitors (specifically including Celebrex) on dogs

recovering from circumflex coronary artery thrombosis. This article concluded that the study “raise[d] concerns regarding an *increased risk of adverse vascular events in patients receiving COX-2 inhibitors*,” and that this “risk may be increased in individuals with underlying inflammatory disorders, including coronary artery disease.” (Emphasis added)

43. A third study, entitled Risk of Cardiovascular Events Associated with Selective COX-2 Inhibitors, by Dr. Debabrata Mukherjee et al. was published in the August 22/29, 2001 issue of the Journal of the American Medical Association (“AMA Study”). This study noted that “[c]urrent data would suggest that use of selective COX-2 inhibitors might lead to increased cardiovascular events,” and that the researcher’s “findings suggest[ed] a potential increase in cardiovascular event rates for the presently available COX-2 inhibitors.” (Emphasis added). This study specifically included Celebrex.

44. The AMA Study went on to conclude that “[g]iven the remarkable exposure and popularity of this new class of medications, *we believe that it is mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents*.” (Emphasis added).

45. The Cleveland Clinic Journal of Medicine published a follow-up to the AMA Study in November, 2001 entitled COX-2 Inhibitors and Cardiovascular Risk: We Defend our Data and Suggest Caution, written by the same authors. This article noted that an “important question[]” raised by the clinical and basic data was “[s]hould COX-2 drugs be avoided in patients with coronary artery disease or its equivalents? Should they be avoided in patients at high risk for coronary artery disease?” The article further concluded that “[u]ntil a cause-and-effect relationship between COX-2 inhibitors and cardiovascular events can be ruled out, *we should exercise caution in prescribing these agents to patients at risk for cardiovascular morbidity*.” (Emphasis added)

46. Additionally, in the FDA’s approval package for Bextra published on or about November 16, 2001 (“BEXTRA Approval Package”), an FDA medical officer noted specific problems with the cardiovascular safety profile of Bextra. Specifically, this officer noted that “[t]he excess of serious cardiovascular thromboembolic [blood clots] in the valdecoxib arm of the CABG [Coronary Artery Bypass Graft] trial is of note as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events,” and that “[g]iven the emerging concern over possible pro-thrombotic actions of certain agents in the COX2 class, these data are of concern.” (Emphasis added).

47. This information was (and is) redacted from the publicly available version of the BEXTRA approval package. Instead, the section containing the statements in the preceding paragraph is replaced with a notation that it “[has] been removed because it contains trade secret and/or confidential information that is not disclosable.” This statement has been made available as a result of a Freedom of Information Act request filed by the advocacy group Public Citizen. That lawsuit alleges the redacted section of the BEXTRA approval package was originally publicly released and was only redacted after complaints from the drug’s developer.

48. There were thus at least four articles in medical journals addressing cardiac risks associated with COX-2 inhibitors, as well as information directly provided to Pfizer by the FDA informing them of this risk. Pfizer was thus plainly aware of the cardiovascular risks associated with both Bextra and Celebrex, and of the need for further research to determine the extent of this risk, from August 2000 onwards.

49. On December 17, 2004, Pfizer issued a press release announcing that it had received new information about the cardiovascular safety of its COX-2 inhibitor Celebrex (celecoxib), based on an analysis of two long-term cancer trials. More specifically, a

government sponsored study conducted for Pfizer by The National Cancer Institute had suspended the use of Celebrex after finding that patients taking 400mg to 800mg of the drug daily were found to have a risk of 2.5 times greater of experiencing major heart problems than those who were not. This level of risk was even greater than the one found in patients taking Vioxx that led Merck to withdraw Vioxx from the marketplace.

### **DEFENDANTS' MISREPRESENTATIONS**

50. On November 1, 2000, Pfizer's 8-K filing with the SEC made reference to a study published in the Journal of American Medicine and claimed that this study demonstrated that "Celebrex showed a positive renal and hepatic profile with *no increase in thromboembolic or other cardiovascular-related events*." (Emphasis added.)

51. This statement was materially false and misleading at the time it was made. In fact, clear evidence of adverse cardiac effects associated with Celebrex were found in the NAS study. The NAS study determined that COX-2 plays an "essential role in the cardioprotection" afforded by Late PC, and COX-2 inhibitors – like Celebrex and Bextra -- entirely prevented these cardioprotective effects. This article concluded that COX-2 was a "cardioprotective protein," offering beneficial cardiac effects, and that drugs blocking this cardioprotective enzyme may neutralize these cardioprotective effects.

52. On December 31, 2001, Pfizer released their 2001 Annual Report, which stated that "In addition to its outstanding GI safety profile, Celebrex has shown *no increased cardiovascular risk compared with traditional arthritis medicines, which distinguishes it from Merck's selective COX-2 inhibitor Vioxx*." (Emphasis added.). This report further stated that "Bextra relieves OA and RA symptoms with only one 10 mg tablet per day, and *safely and effectively treats even the most severe patients*."

53. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

54. Pfizer's March 28, 2002, 10-K SEC filing noted that "Bextra was approved by the FDA in November 2001, for the relief of pain and inflammation of osteoarthritis and adult rheumatoid arthritis and for menstrual pain. We will co-promote Bextra with Pharmacia, which discovered and developed the drug. A launch is planned in 2002."

55. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

56. Pfizer's July 16, 2002 8-K filing with the SEC noted that, "Celebrex and Bextra, COX-2 specific inhibitors discovered and developed by Pharmacia and co-promoted by Pfizer and Pharmacia, continued to extend their lead over competitors. Bextra and Celebrex together currently account for 23.6 percent of audited monthly new prescriptions among U.S. non-steroidal anti-inflammatory drugs in May," and that "Bextra is off to a very good start and has already achieved a 5.6% share of new prescriptions of the NSAID market as of May."

57. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.



58. Pfizer's August 13, 2002 filing with the SEC noted that "Pharmacia's worldwide sales were \$807 million for Celebrex and, \$89 million for Bextra in the second quarter of 2002. Pharmacia's worldwide sales for Celebrex were \$1,414 million in the first six months of 2002, \$710 million in the second quarter of 2001 and \$1,359 million in the first six months of 2001. Pharmacia's worldwide sales for Bextra were \$147 million in the first six months of 2002."

59. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

60. Pfizer's November 13, 2002 10-Q filing with the SEC noted that "Bextra (valdecoxib), discovered and developed by our alliance partner Pharmacia, is used for relief of the pain and inflammation of OA, RA, and primary dysmenorrhea. Bextra was approved by the FDA in November 2001 and launched in the U.S. in April 2002.

61. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

62. December 31, 2002 10-K filing with the SEC stated "[w]ith Celebrex and Bextra, we can offer physicians a broad, extensive portfolio enabling them to treat a wide range of conditions from rheumatoid arthritis, to osteoarthritis, to primary dysmenorrhea (menstrual pain in adults)."

63. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation

study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

64. Pfizer’s 2002 Annual Report, filed with the SEC on March 18, 2003, stated that “[t]he Celebrex launch remains the most successful new prescription product launch ever. By year-end 2002, Celebrex was receiving 22% of total arthritis prescriptions in the U.S.” and that “[d]uring 2002, Pfizer and Pharmacia launched Bextra for OA, RA and primary dysmenorrhea in the U.S. Bextra provides powerful, quick-acting, 24-hour symptom relief with one convenient daily dose. By year-end 2002, Bextra was receiving 8% of total arthritis prescriptions in the U.S.”

65. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the report.

66. Pfizer’s January 22, 2003 8-K filing with the SEC stated that “[s]tudy results presented at the annual meeting of the American College of Rheumatology in October confirmed Bextra’s improved gastrointestinal and cardiovascular safety profiles.”

This filing specifically cited this purported “reconfirmation” of the “cardiovascular safety of Bextra” as an event which would “enhance sales of existing products and strengthen the future product portfolio.”

67. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

68. Pfizer's March 27, 2003 10-K filing with the SEC stated "[w]ith Celebrex and Bextra, we can offer physicians a broad, extensive portfolio enabling them to treat a wide range of conditions from rheumatoid arthritis, to osteoarthritis, to primary dysmenorrhea (menstrual pain in adults)."

69. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

70. In its April 22, 2003 8-K report filed with the SEC, Pfizer stated that "Bextra was launched in the U.S. in April 2002 for the relief of the pain and inflammation of OA and adult RA and for the treatment of primary dysmenorrhea. Since the launch of Bextra, U.S. physicians have dispensed approximately 9.9 million total prescriptions to more than 3.5 million arthritis and dysmenorrhea patients. In June 2003, Bextra achieved an 8.5% share of new prescriptions of the U.S. NSAID market. Celebrex and Bextra together achieved a new-prescription share of 24%."

71. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general – information omitted from the filing.

72. In its July 25, 2003 report on Form 8-K filed with the SEC, Pfizer stated that "We [Pfizer] are continuing to demonstrate Celebrex's safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased*

*cardiovascular risk was found*, relative to both conventional non-steroidal anti-inflammatory drugs (NSAIDs) and placebo.” (Emphasis added.).

73. This report further stated that “Bextra was launched in the U.S. in April 2002 for the relief of the pain and inflammation of OA and adult RA and for the treatment of primary dysmenorrhea. Since the launch of Bextra, U.S. physicians have dispensed approximately 9.9 million total prescriptions to more than 3.5 million arthritis and dysmenorrhea patients. In June 2003, Bextra achieved an 8.5% share of new prescriptions of the U.S. NSAID market. Celebrex and Bextra together achieved a new-prescription share of 24%.”

74. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

75. In its October 22, 2003 8-K filing with the SEC, Pfizer again stated that “We [Pfizer] are continuing to demonstrate Celebrex’s safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional NSAIDs and placebo.” (Emphasis added).

76. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

77. In its October 22, 2003 8-K filing with the SEC, Pfizer again stated that “We [Pfizer] are continuing to demonstrate Celebrex’s safety advantages. In an independent analysis

that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional NSAIDs and placebo.” (Emphasis added).

78. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

79. In their January 22, 2004 8-K filing with the SEC, Pfizer again stated that “We [Pfizer] are continuing to demonstrate Celebrex’s safety advantages. In an independent analysis that included our entire Celebrex arthritis clinical-trial database, *no evidence of increased cardiovascular risk was found*, relative to both conventional NSAIDs and placebo.” (Emphasis added)

80. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

81. Pfizer’s July 21, 2004 8-K filing with the SEC stated that an article in the May 29, 2004 issue of the Lancet “provided further evidence of the cardiovascular safety of Celebrex.”

82. This was materially false and misleading for two reasons: First, at this time the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex. Second, the article actually stated that “*the increased frequency of initiation of treatment for hypertension or congestive heart failure seen in celecoxib users*, although still lower than that of rofecoxib or non-selective NSAIDs, suggests that

celecoxib might not be entirely devoid of clinically important cardiovascular effects”. (Emphasis added.) This data was therefore hardly the evidence of cardiovascular safety Pfizer made it out to be.

83. Pfizer’s August 10, 2004 8-K filing with the SEC contained multiple representations pertaining to the purported cardiovascular safety of Celebrex, including references to the “*established cardiovascular safety*” of Celebrex, to the “*well-documented cardiovascular safety*” of Celebrex, and asserting that there was “*no evidence of a cardiovascular safety signal for Celebrex* in long-term clinical trials of more than 6,000 patients.” (Emphasis added.)

84. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

85. On September 30, 2004, Pfizer issued a press release reacting to Merck’s withdrawal of Vioxx stating “Pfizer is confident in the *long-term cardiovascular safety of Celebrex*” and further asserting that “*Bextra’s cardiovascular safety profile is also well established* in long-term studies.” (Emphasis added.)

86. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

87. On October 1, 2004, Pfizer issued a press release stating that “[t]he evidence distinguishing the cardiovascular safety of Celebrex has accumulated over years in multiple

completed studies, *none of which has shown any increased cardiovascular risk for Celebrex.*” (Emphasis added).

88. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

89. On October 15, 2004, Pfizer issued a press release stating that “[a]vailable clinical information for Bextra suggests there is *no increased risk of cardiovascular thromboembolic events* in people treated for osteoarthritis (OA) and rheumatoid arthritis (RA).” (Emphasis added).

90. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

91. On October 18, 2004, Pfizer issues a press release stating that their “strong confidence in the [cardiovascular] safety of Celebrex is based on the substantial body of experience that has accumulated over several years in multiple completed studies and ongoing trials,” and that “Pfizer remains confident in the long-term cardiovascular safety of Celebrex. “These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

92. Pfizer’s October 20, 2004 8-K filing with the SEC stated that “Celebrex and Bextra continue to perform well by exceeding year-to-date sales projections,” and that Pfizer

expected this “positive trend to continue as more doctors and patients consider Celebrex and Bextra as effective, appropriate treatments.” This filing further stated that available clinical information for Bextra “suggests *no increased risk of cardiovascular thromboembolic events* in patients.”

93. On November 4, 2004, Pfizer issued a press release intended to rebut reports in the Canadian press concerning the cardiovascular safety of Celebrex. This release stated that “[t]he safety profile for Celebrex is well-established and is supported by extensive clinical studies in Canada and around the world,” and that “large scale clinical studies of up to four years . . . showed *no increased cardiovascular safety risk*,” associated with Celebrex. (Emphasis added).

94. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

95. On November 30, 2004 Pfizer issued a press release, in which Karen Katen, executive vice president and president of Pfizer Global Pharmaceuticals proclaimed:

Pfizer’s COX-2 portfolio is led by Celebrex, the world’s most-prescribed arthritis and pain-relief brand. Three ongoing, long-term studies of Celebrex in cancer and Alzheimer’s patients have shown no significant cardiovascular safety concerns. Pfizer is initiating a new long-term study to evaluate the potential cardiovascular benefits of Celebrex in osteoarthritis patients at high-risk for cardiovascular disease. The company also has committed to new clinical trials of Bextra to further study its long-term cardiovascular safety profile. The company looks forward to a “reasoned scientific discussion” about the safety of COX-2 medicines at a U.S. Food and Drug Administration advisory committee meeting in early February, said Joseph M. Feczko, M.D., president, worldwide development and executive vice president of Pfizer Global Research and Development.



96. These statements were materially false and misleading at the time they were made because, as described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitors in general.

97. Defendants' foregoing statements were materially false and misleading at the time that they were made, because each misrepresented and/or omitted the material facts that there was substantial likelihood that Pfizer's Cox-2 inhibitor drugs, Celebrex and Bextra, were unsafe and had potentially dangerous cardiovascular side effects that would limit their marketability (and might result in their removal from the marketplace). As described *supra* at ¶¶ 41-50, the NAS study, the AMA study, and the Circulation study had associated an increased cardiovascular risk with Celebrex and Cox-2 inhibitor drugs in general. Defendants knew or recklessly ignored the fact that these undisclosed dangerous cardiac side effects were common to Cox-2 inhibitor drugs as a class. These severe cardiovascular side effects were likely to limit the long-term marketability of the Celebrex and Bextra products, and posed a serious threat to Pfizer in the form of massive liability to consumers harmed by the use of Bextra and Celebrex.

### **THE TRUTH IS GRADUALLY REVEALED**

98. On October 15, 2004, Pfizer acknowledged for the first time in a press release that Bextra might cause cardiovascular side effects, and announcing that the Company would conduct further studies to examine the safety of the drug. The press release stated in part:

two trials in a high-risk surgery known as coronary artery bypass graft (CABG), an increase in cardiovascular events was observed in patients receiving Bextra alone or in combination with parecoxib. The first study was published last year(1) and the second study was just recently completed. Pfizer emphasized that Bextra is not approved for use in any surgical setting in the United States.

Pfizer will be conducting further studies to confirm the long-term cardiovascular safety profile of Bextra in patients who require chronic treatment for arthritis with a COX-2-specific inhibitor.

99. In reaction to this announcement, CBS MarketWatch reported that Pfizer's share price was being affected by Bextra concerns, having closed down 2% at 28.50 per share.

100. Thereafter, news continued to filter into the market, as the fact gradually dawned that the same problems behind Merck's withdrawal of Vioxx were likely common throughout the Cox-2 inhibitor class of drugs, including Bextra and Celebrex. As piece after piece of the puzzle fell into place, Pfizer's shares dropped again and again in response to the news.

101. On November 4, 2004, The Calgary Herald reported:

Celebrex, a popular pain drug touted as the safe alternative after Vioxx was pulled from drugstore shelves, is suspected of causing at least 14 deaths and numerous heart and brain side-effects, according to Health Canada.

The documents include more than 100 adverse reaction reports on Celebrex in the past five years, including 19 cases of heart attack, cardiac arrest or heart failure, and five strokes. Canadian pharmacists filled about three million prescriptions for the drug last year.

The data, based on voluntary reporting by doctors and others, came to light as some experts suggest Celebrex and other drugs in the same pain-relieving class may have similar effects as Vioxx on the cardiovascular system.

\* \* \*

Health Canada says it is conducting a review of all the "Cox-2 inhibitor" drugs.

Dr. Jim Wright, a pharmacology professor at the University of British Columbia, said more investigation needs to be done on the Cox-2 medication and its effect on the heart.

"We should at this stage be very cautious about the use of these drugs, until such time as the answers are out there," he said. "In my opinion, we don't know for sure whether this is a class effect, but most likely it is."

He noted that Pfizer has launched a major advertising campaign in the U.S., where direct-to-consumer ads by drug companies are permitted, urging former Vioxx users to switch to Celebrex as a safe option.

Dr. Patrice Roy, Pfizer Canada's director of scientific affairs, said the Health Canada adverse reaction information is important, but far from conclusive. Several trials done on the drug have provided no evidence that Celebrex is a threat to heart health, he said.

“You have to look at the data accumulated over time,” said Roy. “This drug has been studied in 30,000 patients, has been prescribed to over 40 million patients worldwide, there are studies actually sponsored by the FDA . . . and basically we haven’t seen anything.”

In fact, he said Pfizer recently announced a major program to investigate whether the drug has properties that could prevent heart problems by affecting inflammation of blood vessels.

The Cox-2 class of drugs, designed to treat pain caused by arthritis and other conditions, are marketed as causing fewer ulcers than other non-steroidal anti-inflammatory drugs such as Aspirin.

Four drugs in the Cox-2 class sold 7.3 million prescriptions in Canada in 2003, racking up combined sales of \$475 million. Vioxx and Celebrex were by far the two most prescribed in the class, outselling Bextra and Mobicox.

Health Canada collects adverse reaction reports from doctors, drug manufacturers and others as a sort of early warning system for safety problems. But it notes the side-effects are only suspected by the people reporting them and not proven. They also contain no information on the patients’ underlying medical conditions and whether those conditions might have played a role in the adverse reaction.

Experts also believe the true number of side-effects is as much as 10 times greater than what is reported to authorities.

The department collected 111 reports on suspected cardiovascular reactions with Celebrex from January 1999 to August 2004, a period during which about 18 million prescriptions for the drug were filled.

Cardiac side-effects ranged from heightened blood pressure to congestive heart failure, cardiac arrest and stroke. The deaths occurred in people whose ages ranged from 48 to 88, although the majority were over 80.

Deaths occurred in as little as a day to months after the patient started taking Celebrex.

By comparison, there were 167 cardiac and brain adverse reaction reports filed on Vioxx in the same period, while just under 16 million prescriptions were sold in Canada. The side-effects included 63 cardiac arrests, heart attacks and heart failures, 28 cases of congestive heart failure and 11 strokes, with 22 deaths reported.

Some concern has been raised about the Cox-2 drugs generally since the Vioxx recall. One theory is that the same drug mechanism that inhibits the inflammation-causing Cox-2 enzymes also encourages blood clotting that can lead to heart attacks and other maladies.

Dr. Garret FitzGerald, a cardiologist at the University of Pennsylvania, published a paper in the New England Journal of Medicine recommending that Cox-2 drugs not be prescribed to people at risk for heart disease, and that manufacturers of the drugs still on the market provide proof they are not harmful.

Health Canada is in the process of collecting safety-related data from around the world on the Cox-2 inhibitors, said Jirina Vlk, a spokeswoman for the department.

If it concludes there is a wider problem, it could order changes to the drugs' product monographs, which outline possible side-effects and recommended uses, or take further action, said Vlk. Health Canada has the power to force drugs from the market.

102. This news further negatively affected Pfizer's share price when President Bush's re-election was buoying other pharmaceuticals stock. In response to this news, Pfizer's share price dropped \$0.39 on November 4, 2004, and another \$0.27 on November 5, 2004.

On November 10, 2004, the New York Times further shocked the market by publishing an article which stated:

The incidence of heart attacks and strokes among patients given Pfizer's painkiller Bextra was more than double that of those given placebos, according to preliminary results of a study presented yesterday at the American Heart Association meeting in New Orleans.

The study, which pooled data from 5,930 patients taking part in 12 trials, found 2.19 times the number of heart attacks or strokes among patients given Bextra, compared with those given placebos. Merck recently withdrew Vioxx, a drug similar to Bextra, after a longer and better-controlled study showed that it doubled the risk of heart attack and stroke.

"The magnitude of the signal with Bextra is even higher than what we saw in Vioxx," Dr. Garret A. FitzGerald, a cardiologist and pharmacologist at the University of Pennsylvania, said in an interview after presenting the data. "This is a time bomb waiting to go off."

Susan Bro, a spokeswoman for Pfizer, said that a heart problem with Bextra appeared only in studies involving patients at very high risk for heart disease who were undergoing cardiac surgery -- a disclosure Pfizer made on Oct. 15. Other studies of Bextra involving 8,000 patients with arthritis who were followed for 6 to 52 weeks found no heart problems, she said.

Dr. FitzGerald is one of the world's leading experts in COX-2 drugs, a class of medicine that includes Vioxx, Bextra and Celebrex, which is also made by Pfizer.

Vioxx had sales of \$2.5 billion last year, while Celebrex had sales of \$1.8 billion and Bextra \$687 million. Celebrex and Bextra have been on their way to bigger sales this year.

In previous studies, Dr. FitzGerald was among the first to explain why COX-2 inhibitor drugs, which were developed to cure pain without causing ulcers, might create heart troubles.

Dr. Curt Furberg, professor of public health sciences at Wake Forest University School of Medicine, helped conduct the study that Dr. FitzGerald announced yesterday. "Basically, we showed that Bextra is no different than Vioxx, and Pfizer is trying to suppress that information," Dr. Furberg said.

The new study of Bextra, however, is not nearly as persuasive as the trial that led to Vioxx's withdrawal because it is backward-looking and simply reorganizes data presented in other settings. Ms. Bro, the Pfizer spokeswoman, said the new study grouped samples that were too disparate for conclusive results.

But Dr. FitzGerald said the latest findings added to growing worries that all COX-2 inhibitors, including Bextra and Celebrex, should be used with great caution.

There is no evidence that Celebrex causes heart problems, Pfizer said.

The FitzGerald study was not the only negative development regarding Bextra. News reports yesterday noted that Pfizer said in a Nov. 5 regulatory filing that the Food and Drug Administration had rejected an application to use Bextra to treat migraines. The company said it was notified in August of the rejection.

Pfizer's stock slipped 25 cents yesterday to close at \$25.99. It declined 38 cents on Monday, as investors digested the company's disclosure that it would probably add a "black box" warning -- the strongest kind -- to Bextra's label. The warning would note that, in rare instances, the drug could cause fatal skin rashes. In its Oct. 15 warning about Bextra's potential risks to patients after heart surgery, Pfizer acknowledged that it had known the results of this study for at least two months before announcing them. During that period, Pfizer representatives said publicly that the company had no evidence that either Celebrex or Bextra caused the kind of heart problems found in a large study of Vioxx.

Bextra is approved to treat arthritis pain. Unlike Vioxx, neither Bextra nor Celebrex has proved to be any safer on the stomach than older, cheaper medicines like ibuprofen or naproxen. Nor has Bextra or Celebrex been shown to alleviate pain any better than those older drugs.

As the COX-2 controversy has continued, the Food and Drug Administration has been criticized by some researchers and medical journal editors for failing to require Vioxx's withdrawal years ago. Yesterday, Health and Human Services Secretary Tommy G. Thompson defended the F.D.A.'s handling of the Vioxx withdrawal.

“You can always be a Monday morning quarterback and say, you know, this could have been done better,” Mr. Thompson said. “I think the F.D.A. just does an outstanding job of protecting Americans’ health.”

Vioxx’s maker, Merck, suffered a financial blow yesterday, as the rating on its \$4.9 billion in long-term debt was cut two levels, to Aa2 from Aaa, by Moody’s Investors Service. The company’s share price has plummeted after the withdrawal of Vioxx, which accounted for 11 percent of the company’s sales last year. Hundreds of lawsuits have been filed by lawyers for patients or their survivors claiming Vioxx caused injuries or deaths.

On Tuesday, Dr. FitzGerald also provided results of his further investigations into the mechanism by which COX-2 medicines may lead to heart troubles. Using mice, Dr. FitzGerald said, he found that inhibiting the COX-2 enzyme might reduce the heart protection of estrogen.

103. In direct reaction to this revelation, Pfizer’s share price dropped further, to a close of \$27.15 on November 11, 2004.

104. On November 18, 2004, FDA reviewer David Graham testified before the Senate Finance Committee that Bextra posed the same risks of serious, potentially life-threatening cardiovascular side effects as Merck’s Vioxx, and further stated that sales of Bextra should be immediately limited or stopped. In particular, Mr. Graham stated:

I would be looking at Bextra very, very closely. That’s a cousin of Celebrex, a cousin of Vioxx. *I think that there is disturbing evidence on that drug, as well*

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[speaking of Dr. Curt Furberg, a colleague] Well, he looks at a paper that gets published on Bextra. I read the paper too, and it’s atrocious what you can do with statistics. And when Curt looked at it, he said, “This is garbage.”

And he reanalyzed the data that were presented in that table (ph), and (inaudible) said, “You analyzed these data correctly, and *you see that there’s a problem with Bextra.*”

And so, being a man who’s based on evidence, who’s an evidence- based scientist, what he said is: *The evidence suggests there’s a problem.*

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I can tell you right now there are at least five drugs on the market today that I think need to be looked at quite seriously to see whether or not they belong

there . . . [after noting one of those five was Bextra] For Bextra, I think that *we're in the same situation we are with Vioxx* in terms of needing to have good studies on cardiovascular risk, and I don't think that we have them.

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105. In reaction to this news, Pfizer's share price continued to drop over the next several sessions, falling to a close of \$26.79 on November 24, 2004.

106. On December 9, 2004, Reuters reported that the FDA was adding a new cardiovascular safety warning to Bextra's label, stating in part:

Pfizer Inc.'s painkiller Bextra will come with a new warning about the possibility of heart attacks and blood clots in patients who have just had heart bypass surgery, the U.S. Food and Drug Administration said on Thursday. The FDA said it still considers the drug beneficial when taken for approved uses, such as relieving arthritis pain.

"FDA believes that, based on what we know now, the overall benefit of Bextra outweighs the risk when used in properly selected patients as directed in the approved labeling," the FDA said in a statement posted on its Web site.

A Pfizer study of more than 1,500 patients who had just had heart bypass surgery found that patients treated with Bextra for pain were more likely to have heart attacks, strokes and blood clots in the legs or lungs than others who took a placebo, the agency said.

Bextra is not approved for treating pain following heart bypass surgery. The new warning specifically urges doctors not to use the drug in that setting.

The updated Bextra label also includes a stronger warning, now highlighted in a black box, about the possibility of a rare, potentially fatal skin reaction known as Stevens-Johnson Syndrome. As of November, the FDA had received 87 reports of that condition and other skin reactions. Thirty-six of the patients were hospitalized and four died, the FDA said.

Bextra is getting close attention from regulators because it is in the same family of drugs as Merck & Co. Inc.'s arthritis pill Vioxx, which was pulled from the market Sept. 30 after a study showed the drug doubled the chances of heart attacks and strokes when used for more than 18 months. Both drugs are so-called COX-2 inhibitors.

Bextra, which was launched in 2001, had sales last year of \$687 million.

Pfizer spokeswoman Mariann Caprino said the company had no comment on the heart warning. “There’s no new information in the label. It’s all been previously shared with the medical community,” she said.

Pfizer announced in October that two small clinical trials of Bextra showed heart bypass patients had an increased risk of stroke and heart attack. The company also said at the time it was adding the skin-related warning to the drug’s packaging.

The FDA is planning a public advisory committee meeting in February to discuss safety concerns with Bextra and other COX-2 inhibitors, including another Pfizer painkiller, Celebrex.

Pfizer shares fell 13 cents, or 0.47 percent, to close at \$27.37 on the New York Stock Exchange.

107. In reaction to this latest news, Pfizer’s shares dropped again, falling to a close of \$27.09 on December 10, 2004.

108. On December 17, 2004, before the stock market opened, Pfizer issued a press release announcing that it had received new information about the cardiovascular safety of its COX-2 inhibitor Celebrex (celecoxib) based on an analysis of two long-term cancer trials. More specifically, a government sponsored study conducted for Pfizer by The National Cancer Institute had suspended the use of Celebrex after finding that patients taking 400mg to 800mg of the drug daily were found to have a risk of 2.5 times greater of experiencing major heart problems than those who were not. This level of risk was even greater than the one found in patients taking Vioxx that led Merck to withdraw Vioxx from the marketplace. The press release issued by Pfizer stated, as follows:

Pfizer Inc said it received new information last night about the cardiovascular safety of its COX-2 inhibitor Celebrex (celecoxib) based on an analysis of two long-term cancer trials.

As reported to Pfizer by the Data Safety and Monitoring Board, one of the studies (the APC cancer trial) demonstrated an increased cardiovascular risk over placebo, while the other trial (the PreSAP cancer trial) revealed no greater cardiovascular risk than placebo.



“These clinical trial results are new. The cardiovascular findings in one of the studies (APC) are unexpected and not consistent with the reported findings in the second study (PreSAP). Pfizer is taking immediate steps to fully understand the results and rapidly communicate new information to regulators, physicians and patients around the world,” said Hank McKinnell, Pfizer chairman and chief executive officer.

Celebrex is approved for use in the United States for the treatment of arthritis and pain, at recommended doses of 100mg to 200mg daily for osteoarthritis and 200mg to 400mg a day for rheumatoid arthritis. It is also approved for a rare condition called familial adenomatous polyposis in doses up to 800mg per day. The APC cancer trial was studied Celebrex at doses of 400mg to 800mg per day. In the PreSAP cancer trial the dose was 400mg per day.

“In placing this new information in context, it is important to understand that the APC trial results differ from both the PreSAP cardiovascular results as well as the large body of data that we and others have accumulated over time, in which an increased risk of serious cardiovascular events in arthritis patients, even at higher-than-recommended doses, had not been seen,” said Dr. Joseph Feczko, president of worldwide development for Pfizer.

“Celebrex is an important medicine that provides necessary pain relief to many patient. Patients being treated with Celebrex should discuss appropriate treatment options with their healthcare professionals. Physicians should factor this new information, as well as ulcer risks and gastrointestinal bleeding seen with traditional NSAIDs, into their prescribing decision.”

In the Adenoma Prevention with Celecoxib (APC) trial, patients taking 400mg and 800mg of Celebrex daily had an approximately 2.5 fold increase in their risk of experiencing a major fatal or non-fatal cardiovascular event compared to those patients taking placebo, according to the National Cancer Institute (NCI). Based on these statistically significant findings, the sponsor of the trial, the NCI, has suspended the dosing of Celebrex in the study.

In a separate long-term study, the Prevention of Spontaneous Adenomatous Polyps (PreSAP) trial, there has been no increased risk for Celebrex patients taking 400mg daily compared with those taking placebo. These findings are based on an identical analysis used to assess cardiovascular risk in the APC trial and conducted by the same independent safety review board. The information from this Pfizer sponsored trial was also received by Pfizer last night and, as with the APC information, was immediately shared by the company with the U.S. Food and Drug Administration.

The two studies, which are following patients over a five-year period, have enrolled a total of about 3,600 patients, some of whom have participated for more than four years. Pfizer estimates that about 2,400 patients evaluated in the cardiovascular analysis have completed two years of treatment.

A third long-term study involving Celebrex in patients at high-risk for Alzheimer's disease is also under way with about 2,000 patients enrolled, about 750 of whom are on 400mg per day of Celebrex. As with the cancer studies, this study is monitored by independent safety experts who meet regularly to assess adverse events. A review by this board as recent as December 10 did not result in any recommendations to change the conduct of this study.

In September and October, the Data Safety and Monitoring Boards of the APC and PreSAP cancer trials conducted a preliminary review of all the then- available data and determined to proceed with the studies. With the cooperation of Pfizer, the safety review boards convened a panel of cardiovascular experts to conduct additional reviews and analyses of the data from these two trials. Last evening, Pfizer received preliminary information resulting from the reviews. The company has not yet received the full analyses of these studies.

As previously announced, Pfizer will continue to work with FDA on the company's plans to sponsor a major clinical study to further assess Celebrex in osteoarthritis patients at high-risk for cardiovascular disease.

#### Additional Information on Celebrex

Patients who have aspirin-sensitive asthma, or allergic reactions to aspirin or other arthritis medicines or certain sulfa drugs called sulfonamides, or who are in their third trimester of pregnancy should not take Celebrex. As with all NSAIDs, serious gastrointestinal tract ulcerations can occur without warning symptoms. Physicians and patients should remain alert to the signs and symptoms of GI bleeding. Celebrex does not affect platelet function and therefore should not be used for cardiovascular prophylaxis. As with all NSAIDs, Celebrex should be used with caution in patients with fluid retention, hypertension, or heart failure. In overall clinical studies the most common side effects of Celebrex were dyspepsia, diarrhea and abdominal pain, which were generally mild to moderate.

109. Reporting on the Pfizer's announcement, *The Wall Street Journal* published an article entitled "Pfizer Says Study Shows Heart Risk From Celebrex" that stated, in relevant part:

Pfizer Inc. said a government-sponsored study of its arthritis drug Celebrex in cancer prevention found a significant risk of cardiovascular problems, an unanticipated result that raise new questions about the safety of the popular drug.

Patients taking Celebrex had a risk of a major cardiovascular event that was two-and-a-half times greater than the risk for patients taking placebo. That level of risk was even greater than the one found in patients taking Vioxx in a similar trial that led Merck & Co. to withdraw Vioxx in late September. That study, called Approve, detected a doubling of risk of heart attacks and strokes in patients taking the daily pill longer than 18 months.

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The worrisome study of Celebrex, called the Adenoma Prevention with Celecoxib trial, involved patients taking 400mg and 800mg of Celebrex daily to see if the drug could prevent colon cancer. The National Cancer Institute, which sponsored the study, stopped giving patients Celebrex after learning of the increased risk to patients during a review of the data.

“These new data in Celebrex users should send a strong message to patients and clinicians that its use should be strongly restricted in patients with a diagnosis of coronary artery disease or its risk factors such as high blood pressure, high cholesterol, diabetes or a family history” said A. Mark Fendrick, a professor of medicine at the University of Michigan in Ann Arbor. “Data from other drugs in the Cox-2 inhibitor class -- Vioxx and Bextra -- had already raised a warning signal about their use in people at risk for heart attacks and strokes. People on either Celebrex or Bextra should talk to their doctor immediately about the risk and benefit of the drug for them.”

Pfizer Chief Executive Henry McKinnell said in a statement, “Pfizer is taking immediate steps to fully understand the results and rapidly communicate new information to regulators, physicians and patients around the world.” (See Pfizer’s statement.)

Celebrex is approved for use in the U.S. for the treatment of arthritis and pain. The dose used in the cancer trial that found a risk was two-times or more the recommended dose for of 100mg to 200mg for osteoarthritis, the most common form of joint pain.

Pfizer’s other Cox-2 drug, Bextra, was recently given a new FDA label warning of increased risk of heart attack and blood clots in patients who recently had coronary bypass surgery.

Prescriptions in Bextra and Celebrex rose sharply after the Vioxx recall. Prescriptions for Celebrex increased by 40% in the two months after Vioxx was removed from the market on the last day of the third quarter.

In the third quarter, Celebrex sales rose 14% to \$797 million; Bextra sales rose 37% to \$324 million in the quarter.

### **CAUSATION ALLEGATIONS**

110. Pfizer’s common stock was traded on the New York Stock Exchange at all relevant times. As described *supra*, Defendants’ material misrepresentations and omissions had the effect of creating and maintaining an artificially inflated price for Pfizer’s securities. Those misrepresentations and omissions that were not immediately followed by an upward movement

in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting the false public perception of Pfizer and Celebrex and Bextra.

111. Defendants had a duty to promptly disseminate accurate and truthful information with respect to Pfizer's financial and operational condition or to cause and direct that such information be disseminated and to promptly correct any previously disseminated information that was misleading to the market. As a result of their failure to do so, the price of Pfizer's stock was artificially inflated during the Class Period, damaging Plaintiff and the Class.

112. Defendants' false and misleading statements and omissions in their press releases and other public statements directly caused losses to the Class. On the strength of these false statements, misrepresentations and material omissions in its press releases, announcements and other public statements concerning its financial condition, the Company's stock was artificially inflated to a Class Period high of \$48.06 per share on December 20, 2000, and remained artificially inflated until the end of the Class Period. Thereafter, the stock fell to as low as \$21.99 on December 17, 2004, thereby inflicting substantial damages on Plaintiff and the Class. Until shortly before Plaintiff filed this Complaint, he was unaware of all of the facts, as described herein, and could not have reasonably discovered the Defendants' fraudulent scheme by the exercise of reasonable diligence.

#### **DEFENDANTS ACTED WITH SCIENTER**

113. Each misrepresentation and/or omission of material fact alleged herein was made with reckless disregard for, or knowledge of its false and misleading nature. At all relevant times, each Defendant knew the material facts regarding the Cox-2 inhibitor class-wide risk of severe cardio-vascular side effects and the impact such side-effects could have on the Company and the Company's sales of its Celebrex and Bextra products. Thus, the misrepresentations and

omissions complained of herein were made with the Defendants' knowledge, or with deliberate recklessness.

114. Defendant McKinnel had the opportunity to commit and participate in the fraud described herein. Defendant McKinnel was the Chief Executive Officer of Pfizer, and thus controlled the Company's press releases, corporate reports, SEC filings and communications with analysts.

115. Defendants had the motive to commit and participate in the fraud. The Company wished to continue to market these drugs and garner the revenues and earnings from their sales, and McKinnel wished to continue to receive his compensation based on these revenues and earnings.

116. As set forth at ¶¶ 20-29, *supra*, Defendants were on notice at all times during the Class Period about the class-wide deleterious and dangerous cardiovascular effects of Cox-2 inhibitors drugs, including Celebrex and Bextra. Thus, Defendants knew or recklessly disregarded the negative facts alleged herein at all relevant times. Nevertheless, Defendants acted to suppress and conceal the truth about Celebrex and Bextra from consumers and from investors, and actively misrepresented the safety of these products throughout the Class Period.

#### **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

117. Plaintiff brings this action derivatively in the right and for the benefit of Pfizer to redress injuries suffered, and to be suffered, by Pfizer as a direct result of the breaches of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. Pfizer is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

118. Plaintiff will adequately and fairly represent the interests of Pfizer in enforcing and prosecuting its rights.

119. Plaintiff is the owner of the stock of Pfizer during all times relevant to the Individual Defendants' wrongful course of conduct alleged herein, and remain shareholders of the Company.

120. The Board at the time this complaint was filed consisted of the following individuals: defendants McKinnell, Steere, Vallès, Brown, Burns, Burt, Cornwell, Gray, Horner, Howell, Ikenberry, Lorch, Mead, Raines, and Simmons. Plaintiffs did not make any demand on the Board to institute this action because such a demand would have been futile, wasteful and useless act, particularly for the following reasons:

(a) The principal professional occupation of defendant McKinnell is his employment with Pfizer, pursuant to which he received and continues to receive substantial monetary compensations and other benefits. Specifically, for FY:03, Pfizer paid defendant McKinnell \$6,650,100 in salary and bonuses, \$249,390 in other compensation, and granted him 1,000,000 options to purchase. Accordingly, defendant McKinnell lacks independence from defendants Burns, Lorch, Mead and Raines, defendants who are not disinterested and/or independent and who exert influence over defendant McKinnell's compensation by virtue of their positions on the Board and the Compensation Committee. This lack of independence renders defendant McKinnell incapable of impartially considering a demand to commence and vigorously prosecute this action;

(b) In connection with his retirement, Pfizer into a consulting agreement with Defendant Steere, which provides that Steere serve as Chairman Emeritus of the Company and, when and as requested by the Chief Executive Officer, will provide consulting services and

advice to the Company and participate in various external activities and events for the benefit of the Company. Moreover, the agreement requires Steere to obtain the approval of the Board of Directors before providing any consulting services, advice or service of any kind to any other company or organization that competes with Pfizer. The Company pays Steere (i) an annual retainer of \$50,000; (ii) a fee of \$5,000 for each day he renders services; (iii) reimbursement for travel and living expenses; and (iv) access to Company facilities and services comparable to those that were made available to him by the Company prior to his retirement. Because of the compensation he receives from Pfizer, and the necessity to obtain permission from all other board member before he can render services to other companies in the drug industry, Steere is not independent from the other boards members and would not take a position contrary to them or the Company. This lack of independence renders defendant Steere incapable of impartially considering a demand to commence and vigorously prosecute this action.

(c) Defendant Vallès has long standing business ties to the Company. Vallès, is Chairman Emeritus of Minerals Technologies Inc. (MTI), and was previously Chairman and CEO of Minerals Technologies Inc., when MTI became a publicly traded company through an initial public offering from Pfizer Inc. on October 23, 1992. Vallès joined Pfizer in 1968 as an Economist and Assistant to the Chairman. In 1970, he was appointed Director of Corporate Planning and Information Services, and, in 1972, was elected Controller of the company. In 1980, he was elected to the Board of Directors of Pfizer Inc., and became Vice President-Finance in June 1980 and was elected Senior Vice President-Finance in January 1989. In April 1989, he was given responsibility for Pfizer Specialty Minerals Group, the operations that now comprise Minerals Technologies Inc. In August 1990, he was elected Senior Vice President and assumed the added responsibility for the company's Animal Health group. He was elected Executive Vice

President in February 1991 when he also became responsible for the Pfizer Specialty Chemicals Group. On January 1, 1992, Mr. Vallès was given the additional responsibility for the Pfizer Hospital Products group and, on March 1, 1992, he was elected Vice Chairman of Pfizer Inc. As a result of these long standing ties to Pfizer, and the fact that he has earned virtually all of his income from his professional employment with Pfizer and its affiliates, defendant Vallès lacks independence from the remainder of the board, including defendant Steere who was Chairman and CEO during the time in which MTI was spun off from Pfizer and Vallès became Chairman and CEO of MTI as a separate entity. This lack of independence renders defendant Vallès incapable of impartially considering a demand to commence and vigorously prosecute this action;

(d) The directors of the Board receive the following compensation: (i) all outside directors receive \$26,000 per year; (ii) committee members receive \$4,000 additional per year; (iii) committee chairs receive \$6,000 additional per year; (iv) members of the Science and Technology Committee receive an additional \$8,000 per year; (v) the chair of the Science and Technology Committee receives an additional \$16,000 per year; and (vi) each member also receives an annual award of 3,600 units, consisting of rights to purchase Pfizer common stock. This compensation creates debilitating conflicts for the Director Defendants, who will not jeopardize this lucrative compensation by taking the action plaintiff requests;

(e) Pursuant to the Pfizer's most recent Proxy ("Proxy"), the Director Defendants held substantial holdings of Pfizer common stock. Specifically, McKinnell had 1,304,166 shares and options to purchase 2,629,158 exercisable within 60 days; Steere, 1,966,691 shares and options for 4,226,950 shares; Vallès 898,235 shares and 93,329 stock equivalent units in the deferred compensation plan; Brown, 1,200 shares and 36,626 stock



equivalent units; Burns 20,400 shares and 43,089 stock equivalent units; Burt 2,200 shares and 33,796 stock equivalent units; Cornwell 1,000 shares and 42,847 stock equivalent units; Gray 907 shares and 58,410 stock equivalent units; Horner 11,296 shares and 43,089 stock equivalent units; Howell 6,350 shares and 52,278 stock equivalent units; Ikenberry 48,516 shares and 139,101 stock equivalent units; Lorch 1,750 shares and 33,795 stock equivalent units; Mead 9,350 shares and 41,948 stock equivalent units; Raines 1,500 shares and 35,048 stock equivalent units; and Simmons 879 shares and 43,107 stock equivalent units. Thus, none of these defendants would take the action request by plaintiff as they would not risk the consequence of these options expiring upon their resignation or removal from the Board;

(f) According to Pfizer's Proxy, defendants Brown, Ikenberry and Raines were, during the relevant period, the members of the Science and Technology Committee. This Committee was responsible for periodically examining management's direction and investment in the Company's pharmaceutical research and development as well as in its technology initiatives. The Committee was further responsible for determining whether there was sufficient and ongoing external review from world-class experts across both research and development, pertaining to the Company's therapeutic areas, including with regard to its pharmaceutical products such as Celebrex and Bextra which constituted a material portion of the Company's revenues. The Science and technology Committee met only two times in fiscal year 2003, and failed to require the Company to conduct additional studies or publish known results of the existing studies set forth supra at paragraphs 41-50. By such actions, defendants Brown, Ikenberry and Raines breached their duties by causing or allowing the false statements set forth above without the inclusion of adverse information pertaining to Celebrex and Bextra as

described above. As a result of these defendants' breach of their duties, any demand upon them is futile;

(g) The entire Pfizer Board and senior management participated in the wrongs complained of herein. Pfizer's directors are not disinterested or independent since each of the Director Defendants served on the Pfizer Board during the Relevant Period. Pursuant to their specific duties as Board members, each was charged with the management of the Company and to conduct its business affairs. Each of the above-referenced defendants breached the fiduciary duties that they owed to Pfizer and its shareholders in that they failed to prevent and correct the false and misleading statements concerning Celebrex and Bextra and the Company's financial prospects including the sales of these products. Thus, the Pfizer Board cannot exercise independent objective judgment in deciding whether to bring this action or whether to vigorously prosecute this action because its members are interested personally in the outcome as it is their actions that have subjected Pfizer to millions of dollars in liability for product defect actions, including wrongful death actions, possible violations of applicable securities laws, and ongoing investigations by the FDA;

(h) The Individual Defendants, because of their inter-related business, professional and personal relationships, have developed debilitating conflicts of interest that prevent the Board members of the Company from taking the necessary and proper action on behalf of the Company as requested herein. In addition to the conflicts that exist as a result of their participation in the improper accounting and insider selling, as detailed herein supra, the majority of the Board, including the defendants listed below, are subject to the following prejudicial entanglements:

(i) Defendants Horner and Gray have longstanding business ties by virtue of serving jointly as members of the board of directors of Prudential Financial, Inc., in addition to Pfizer;

(ii) Defendants Gray and Burns have longstanding business ties by virtue of serving jointly as members of the board of directors of J.P Morgan Chase & Co., in addition to Pfizer.

(iii) Defendants McKinnell and Howell have longstanding business ties by virtue of serving jointly as members of the board of directors of ExxonMobil Corp., in addition to Pfizer.

(iv) Defendants Burns and Howell have longstanding business ties by virtue of serving jointly as members of the board of directors of J.C. Penney Co., Inc., in addition to Pfizer.

(k) The Director Defendants of Pfizer, as more fully detailed herein, participated in, approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from Pfizer's stockholders or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties;

(l) In order to bring this suit, all of the directors of Pfizer would be forced to sue themselves and persons with whom they have extensive business and personal entanglements, which they will not do, thereby excusing demand;

(m) The acts complained of constitute violations of the fiduciary duties owed by Pfizer's officers and directors and these acts are incapable of ratification;

(n) Each of the Director Defendants of Pfizer authorized and/or permitted the false statements disseminated directly to the public or made directly to securities analysts and which

were made available and distributed to shareholders, authorized and/or permitted the issuance of various of the false and misleading statements and are principal beneficiaries of the wrongdoing alleged herein, and thus could not fairly and fully prosecute such a suit even if such suit was instituted by them;

(o) Any suit by the current directors of Pfizer to remedy these wrongs would likely expose the Individual Defendants and Pfizer to further violations of the securities laws that would result in civil actions being filed against one or more of the Individual Defendants, thus, they are hopelessly conflicted in making any supposedly independent determination whether to sue themselves;

(p) Pfizer has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants and current Board have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Pfizer any part of the damages Pfizer suffered and will suffer thereby;

(q) If the current directors were to bring this derivative action against themselves, they would thereby expose their own misconduct, which underlies allegations against them contained in class action complaints for violations of securities law, which admissions would impair their defense of the class actions and greatly increase the probability of their personal liability in the class actions, in an amount likely to be in excess of any insurance coverage available to the Individual Defendants. In essence, they would be forced to take positions contrary to the defenses they will likely assert in the securities class actions. This they will not do. Thus, demand is futile; and

(r) If Pfizer's current and past officers and directors are protected against personal liability for their acts of mismanagement, abuse of control and breach of fiduciary duty alleged in

this Complaint by directors' and officers' liability insurance, they caused the Company to purchase that insurance for their protection with corporate funds, i.e., monies belonging to the stockholders of Pfizer . However, due to certain changes in the language of directors' and officers' liability insurance policies in the past few years, the directors' and officers' liability insurance policies covering the defendants in this case contain provisions that eliminate coverage for any action brought directly by Pfizer against these defendants, known as, *inter alia*, the "insured versus insured exclusion." As a result, if these directors were to sue themselves or certain of the officers of Pfizer, there would be no directors' and officers' insurance protection and thus, this is a further reason why they will not bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage exists and will provide a basis for the Company to effectuate recovery. If there is no directors' and officers' liability insurance at all then the current directors will not cause Pfizer to sue them, since they will face a large uninsured liability.

121. Moreover, despite the Individual Defendants having knowledge of the claims and causes of action raised by plaintiff, the current Board has failed and refused to seek to recover for Pfizer for any of the wrongdoing alleged by plaintiff herein.

122. Plaintiff has not made any demand on shareholders of Pfizer to institute this action since such demand would be a futile and useless act for the following reasons:

(a) Pfizer is a publicly held company with over 7.5 billion shares outstanding, and thousands of shareholders;

(b) Making demand on such a number of shareholders would be impossible for plaintiff who has no way of finding out the names, addresses or phone numbers of shareholders; and

(c) Making demand on all shareholders would force plaintiff to incur huge expenses, assuming all shareholders could be individually identified.

### **FIRST CAUSE OF ACTION**

#### **Against All Defendants for Breach of Fiduciary Duty**

123. Plaintiff incorporates by reference and reallege each and every allegation contained above, as though fully set forth herein.

124. The Individual Defendants owed and owe Pfizer fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Pfizer the highest obligation of good faith, fair dealing, loyalty and due care.

125. The Individual Defendants, and each of them, violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.

126. Each of the Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly misrepresent the Company's products, including Celebrex and Bextra, and the Company's financial prospects with respect to the sale of such products and failed to correct the Company's public statements and publicly reported financial guidance. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

127. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, Pfizer has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

128. Plaintiff on behalf of Pfizer has no adequate remedy at law.

## **SECOND CAUSE OF ACTION**

### **Against All Defendants for Abuse of Control**

129. Plaintiff incorporates by reference and reallege each and every allegation contained above, as though fully set forth herein.

130. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Pfizer, for which they are legally responsible.

131. As a direct and proximate result of the Individual Defendants' abuse of control, Pfizer has sustained significant damages.

132. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

133. Plaintiff on behalf of Pfizer has no adequate remedy at law.

## **THIRD CAUSE OF ACTION**

### **Against All Defendants for Gross Mismanagement**

134. Plaintiff incorporates by reference and reallege each and every allegation contained above, as though fully set forth herein.

135. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Pfizer in a manner consistent with the operations of a publicly held corporation.

136. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Pfizer has sustained significant damages in excess of hundreds of millions of dollars.

137. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

138. Plaintiff on behalf of Pfizer has no adequate remedy at law.

#### **FOURTH CAUSE OF ACTION**

##### **Against All Defendants for Waste of Corporate Assets**

139. Plaintiff incorporate by reference and reallege each and every allegation contained above, as though fully set forth herein.

140. As a result of the false and misleading statements set forth above, misrepresenting to investors the safety of Celebrex and Bextra along with the Company's business prospects from the sale of these products, and by failing to properly consider the interests of the Company and its public shareholders by failing to conduct proper supervision, defendants have caused Pfizer to waste valuable corporate assets by paying incentive based bonuses to certain of its executive officers and incur potentially millions/billions of dollars of legal liability and/or legal costs to defend defendants' unlawful actions.

141. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

142. Plaintiff on behalf of Pfizer has no adequate remedy at law.

#### **FIFTH CAUSE OF ACTION**

##### **Against All Defendants for Unjust Enrichment**

143. Plaintiff incorporates by reference and reallege each and every allegation set forth above, as though fully set forth herein.

144. By their wrongful acts and omissions, defendants were unjustly enriched at the expense of and to the detriment of Pfizer.

145. Plaintiff, as a shareholder and representative of Pfizer, seeks restitution from these defendants, and each of them, and seek an order of this Court disgorging all profits, benefits and



other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiffs demand judgment as follows:

A. Against all of the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment;

B. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiffs on behalf of Pfizer have an effective remedy;

C. Awarding to Pfizer restitution from the defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the defendants;

D. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

### **JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: December 21, 2004

FARUQI & FARUQI, LLP

By: /s/ Nadeem Faruqi

NADEEM FARUQI

SHANE ROWLEY

DAVID LEVENTHAL

320 East 39<sup>th</sup> Street

New York, NY 10016

Telephone: 212/983-9330

Facsimile: 212/983-9331

*Counsel for Plaintiff*

### VERIFICATION

I, Nadeem Faruqi, hereby declare as follows:

1. I am a member of the law firm of Faruqi & Faruqi, LLP, counsel for plaintiff in the above-entitled action. I have read the foregoing complaint and know the contents thereof. I am informed and believe the matters therein are true and on that ground allege that the matters stated therein are true.
2. I make this Verification because plaintiff is absent from the County of New York where I maintain my office.

Executed this 21st day of December, 2004, at New York, New York.

/s/ Nadeem Faruqi  
Nadeem Faruqi